Quarterly Progress Report #2

N01-NS-5-2365

Restoration of Hand and Arm Function by Functional Neuromuscular Stimulation

Period covered: January 1, 2006 to March 31, 2006

Principal Investigator: Robert F. Kirsch, Ph.D.

Program Manager: William D. Memberg, M.S.

Case Western Reserve University
Wickenden 115
10900 Euclid Avenue
Cleveland, OH 44106-7207
216-368-3158 (voice)
216-368-4969 (FAX)
rfk3@case.edu

A. Executive Summary

1. Contract goals

The overall goal of this contract is to develop and deploy a family of neuroprostheses that can restore arm and hand function to almost any individual with significant paralysis due to cervical spinal cord injury. This contract includes three primary components that are aimed at making this possible:

a. Technology development

i. Development of an implantable 4-channel EMG module by an industrial partner
ii. Purchase of an implantable 8-channel stimulation module from an industrial partner
iii. Development of a fully implanted bipolar EMG electrode

b. Neuroprosthesis deployment

i. 8-channel stimulation, switch-controlled neuroprosthesis for C6 SCI (4 participants)
ii. 16-channel stimulation, 8-channel EMG controlled neuroprosthesis for C5-C6 SCI (4 participants)
iii. 16-channel stimulation, 8-channel EMG controlled neuroprosthesis for C1-C4 SCI (1 participant)

c. Development of high performance command and control interfaces

i. EMG-based control approaches
ii. Integration of brain-machine interfaces into neuroprosthesis control

2. Overview of this reporting period

During this three-month period, we have finalized the work schedule for the implantable EMG module and fabricated a prototype of an intramuscular MES electrode recording tip. Control schemes were evaluated for a virtual arm, and a double-jaw-clench mode switch was implemented.

B. Activity Summary

- Subcontract with NDI Medical to develop a four-channel implantable EMG module was completed and signed. The work schedule was finalized.
- A design review meeting was held for the intramuscular MES electrode. An initial prototype of the recording tip was fabricated.
- A 2-degree-of-freedom real-time model was integrated with a virtual arm. Various control schemes were evaluated, including proportional-derivative, equilibrium point and fuzzy.
- EMGs associated with rapid double jaw clenches were evaluated as a robust mode switch in able-bodied and SCI subjects. Real-time implementation of a double jaw clench mode switch was done in an FES subject's computer-based EMG training program.

C. Research Results and Discussion

1. *Development of implantable 4-channel EMG module*

Rationale:

All of the neuroprosthesis systems to be deployed during this contract will utilize the Micropulse family of implanted stimulators, and many of these will use a user command and control interface based on EMG recordings from muscles with retained voluntary function. We are subcontracting with NDI Medical to develop a 4-channel implantable Micropulse EMG module that is easily integrated into a neuroprosthesis system that also includes one or more stimulation modules.

Results:

During the second quarter of this project, the subcontract between Case Western Reserve University and NDI Medical was completed and signed. Members of the Case team met twice with NDI Medical to put in place a process for the development, testing, and fabrication of the Micropulse EMG module, and to finalize a work schedule. The work schedule is summarized in the table below.

Discussion and interpretation:

When this two-year subcontract is completed, NDI Medical will be ready to deliver fully-functional four-channel implantable EMG modules for use in the neuroprosthesis systems deployed to be deployed under this contract.

Future plans:

The schedule for the entire two-year subcontract is summarized below. During the third quarter, several design specifications will be determined, including:

- The minimum distance between adjacent Micropulse modules (stimulation or EMG).
- The maximum stimulation frequency to be available for different electrode types (e.g., muscle-based or nerve cuff).
- Methods for reducing stimulation artifacts in the EMG recordings.

Deliverable	Date
Specify battery and power management requirements (MPII)	4/30/06
Select supplier and start tooling (MPII)	7/31/06
Specify interface to External Controller	9/30/06
Simulate and prototype MES acquisition summary & firmware	11/30/06
Measure & test wireless communications hardware (MPII)	12/31/06
Complete verification testing of MES acquisition circuitry	12/31/06
Finalize wireless communication protocol	1/31/07
Finalize packaging and sterilization (MPII)	1/31/07
Finalize MES processing software	Case
Finalize IPG circuitry	1/31/07
Layout flex circuit	3/31/07
First article circuit board assemblies	7/31/07
Complete manufacturing process validation	8/31/07
Complete finished product qual. testing & docs for IDE submission to FDA	9/30/07

2. Development of a Fully Implanted Intramuscular Bipolar MES Electrode

Activity Summary:

- A design review meeting was held to discuss the proposed design of the intramuscular MES electrode, focusing on the needed modifications from the intramuscular stimulation electrode design.
- A prototype of the intramuscular MES electrode tip was fabricated.

Rationale:

We currently use epimysial-based MES electrodes in our stimulation systems. While these work well, the epimysial recording electrodes may be difficult to implant if the target muscle is small or deep. Epimysial electrodes also require surgical incisions to expose the target muscles, and their implantation can be time-consuming if many electrodes are being implanted

The intramuscular stimulating electrode (IM-STIM) that we use is able to access small and/or deeper muscles of the hand and forearm while minimizing incision size and implantation time. The IM-STIM electrode has been shown to have excellent tissue response characteristics and long-term durability. It is anticipated that modifying the IM-STIM design to create an intramuscular bipolar MES electrode (IM-MES) would provide similar benefits.

Results:

Design Review

A design review meeting was held to discuss the proposed design of the IM-MES electrode. The design components of the IM-STIM electrode were discussed to determine which parts needed to be modified to create a bipolar MES recording electrode.

Lead – no changes are needed, since it already has two separate helically-wound conductors.

Connector end – depends upon the device to which it is to be attached. For the Micropulse-style devices, an industry-standard bipolar IS-1 connector can be used. For the IST-style devices, a Y-branch connector can be used.

Distal tip – instead of combining the two deinsulated conductors together when wrapping them around the outside of the tubing (as is done in the IM-STIM electrode), the conductors will be deinsulated at different lengths, and wrapped around the tubing in different locations to allow for bipolar recording. It was decided that the initial IM-MES size parameters should be similar to the epimysial MES electrodes (4 mm long recording areas separated by 6 mm).

Anchor – no changes are needed

Insertion Tool – Since the connector end will be an IS-1 connector or a Y-branch lead, both of which are larger than the IM-STIM single-conductor connector, the IM-STIM insertion sheath will be too small. Alternatives will be investigated, including larger diameter sheaths and pealable sheaths that are used for other medical implant leads.

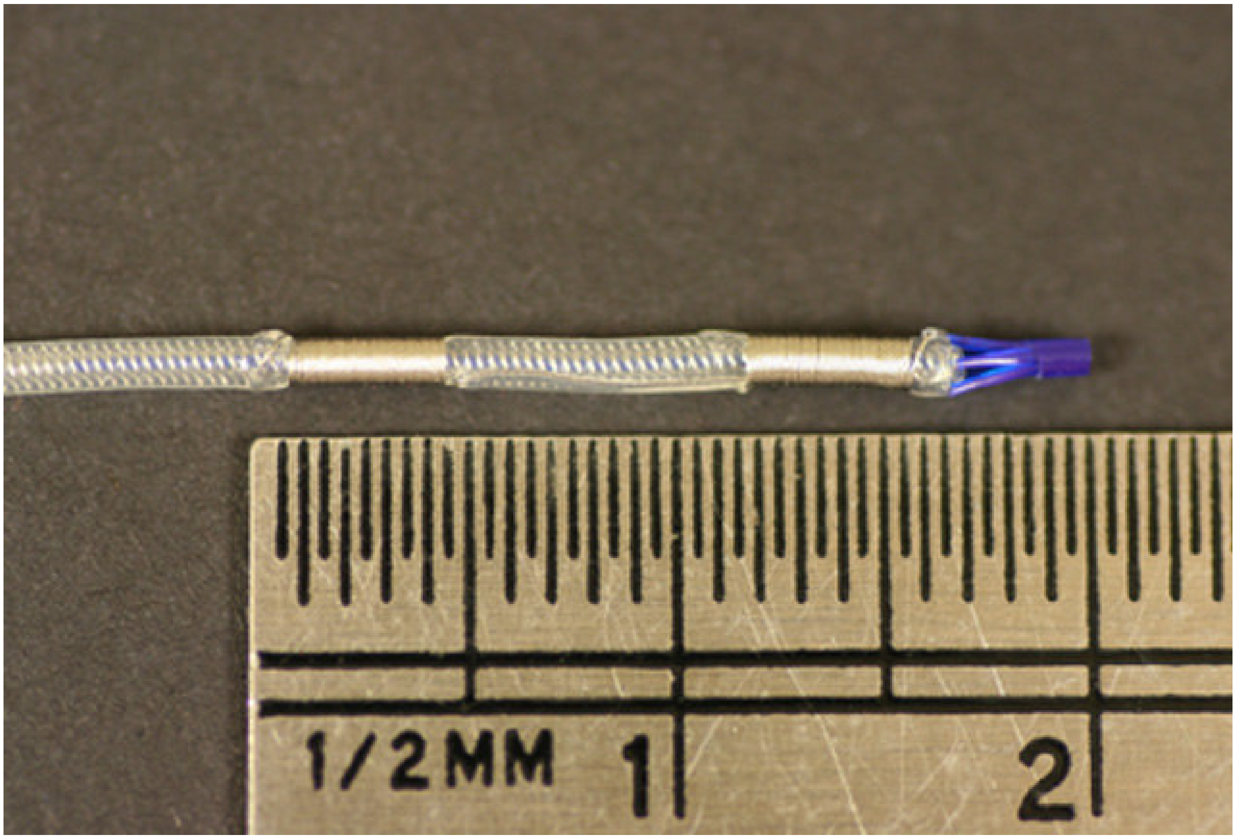

Figure 1. IM-MES electrode prototype tip.

Recording Tip Prototype

A prototype of the IM-MES electrode tip was fabricated using the following technique. One of the two conductors was deinsulated where it exits the tube and was then wrapped around the outside of the tubing (Figure 1) for 4 mm and was then inserted back into the tubing. The second conductor was fed back inside the tubing to a small hole in the tubing 10 mm from the end. It then exited the tubing, was deinsulated, then wrapped around the tubing for 4 mm and inserted back into the tubing. The insertion holes in the tubing were sealed with silicon adhesive.

<u>Discussion and interpretation</u>:

The initial prototype of the stimulating tip satisfied the design specifications for the IM-MES and was not difficult to fabricate. Although other variations will be examined, it appears that the IM-MES recording tip should be easy to manufacture.

The only other issue in the electrode design appears to be the insertion sheath.

<u>Future plans</u>:

Other variations in the technique for winding the recording tip will be examined, to determine the optimal design.

Also, commercially available pealable sheaths will be investigated to see whether they would be useful for the IM-MES insertion.

3. Development of a real-time model of the human arm and hand

Activity Summary

- 2-DOF real-time model integrated with virtual arm.
- Various control schemes evaluated, including proportional-derivative, equilibrium point and fuzzy.

Rationale

The output of the real-time model (RTM) has been integrated with the VR framework, allowing the results of model simulations to be viewed in real-time in the virtual reality environment. Matlab's internal virtual reality viewer allows viewing of the simulations on the same computer that the RTM is running on, and the web framework allows simulation results to be viewed across a network. This will be important for future versions of the model as updating the graphics reduces the processing power available for model simulations.

Much of the effort during this reporting period has been spent on control issues. Previously, a test version of the model used end-point control to test the speed of the model. In that version, controller gains were specific to a particular arm configuration, and were set at the muscle level. This worked well for that test, but is unsuitable for the general case of a moving arm due to system non-linearities. Various types of control were considered.

The 2-DOF model comprises two single degree-of-freedom joints with six actuators (muscles). Two of the actuators are bi-articular and there is system redundancy. The actuators have length- and velocity-dependent force-generating capabilities, which introduce a further non-linearity on top of the kinematic coupling between the two segments. Control of even such simple non-linear system is non-trivial, and three types of controller were considered.

Firstly, it was hypothesized that accounting for the length dependency of the muscle forces would sufficiently linearise the system to allow proportional-derivative (PD) control. Figure 2 shows the scheme for a PD controller. Linearization of the system is carried out in the block "Map" by calculating the required muscle activations as a function of muscle length as well as required torque.

Figure 2. Scheme for PD controller with muscle map for distributing forces across muscles.

Secondly, an equilibrium point controller was considered. In the equilibrium point hypothesis, muscles may be assumed to act as springs with a certain zero-force length and a certain stiffness. The system may then be controlled by adjusting those parameters, which forces the system to find a new equilibrium point. Theoretically, this allows for simple control of complex systems. In order to implement such a controller, though, a map relating joint angles to muscle zero-force length is required. As the zero-force length of the muscles is activation-dependent though, this map is not constant. This was felt to be a serious problem even for this small scale system, and so this idea was not pursued.

Finally, a hybrid controller featuring a feed-forward stage and a fuzzy PD feedback stage was considered. The feed-forward stage comprises a neural network trained to predict the muscle activations needed to move the model from one position to another. This network is trained on the basis of extensive inverse-dynamic simulations in which muscle activations are calculated based on input kinematics. The feedback stage of the controller is a type of PD controller, but with "fuzzy" rules. This is better able to cope with system non-linearities than a conventional PD controller.

Results

Figure 3 shows the change in joint angles following a single end-point position command as input, using the simple PD controller. The vertical axis shows the error between the desired joint angles and the actual angles. The error should of course drop to zero when the system reaches a steady state. It can be seen that while the system is stable, the steady-state error is very high.

The hybrid controller is still under development, and so results are not yet available.

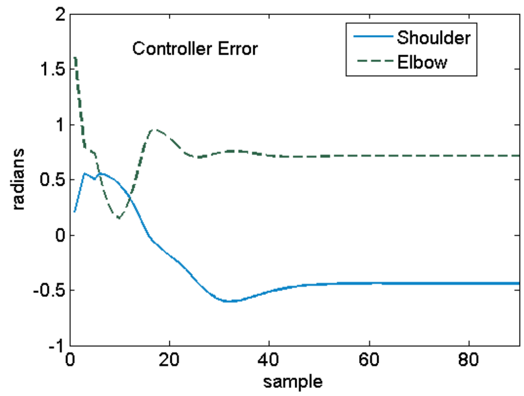

Figure 3. Joint angles controlled by a simple PD controller, with high stead-state error.

Discussion and Interpretation

The simple PD controller was not able to adequately control the system. Gains low enough to ensure stability of the system resulted in an unacceptably high steady-state error. Increasing the gains in an attempt to reduce that error resulted in instability of the system. The reason for this is that the system remains very non-linear (due to kinematic coupling) even after correction for the length dependency of the muscles. This type of controller would become increasingly hard to implement as the size of the system increased. This lack of scalability combined with the difficulties in implementing it even for a 2-DOF system suggest that it is inappropriate for the Dynamic Arm Simulator.

The hybrid controller effectively removes the kinematic coupling from the feedback stage by using a feed-forward component to put the arm in approximately the right position and using feedback only for correcting for small errors about a fixed endpoint. For small displacements about a fixed endpoint, the system can be assumed to be linear. Furthermore, the feed-forward stage requires no system knowledge as the coefficients are entirely empirically determined. It is expected that this controller will scale well to higher DOF systems, and thus will be suitable in the long term for all future DAS versions.

Future Plans

Work during the next period will concentrate initially on finalizing DAS1. Specifically, the feed-forward part of the hybrid controller (the map) will be generated in the next few days. The feedback component has already been developed but cannot be optimized without the feed-forward part.

Following DAS1, work will begin on DAS2, the 5-DOF model. DAS2 will comprise a 3-DOF gleno-humeral joint and a 2-DOF elbow joint, as outlined in the roadmap in the previous progress report.

4. Development of a Mode Switch for Increased Dimensions of Command

Activity Summary:

- Evaluation of EMGs associated with rapid double jaw clenches as a robust mode switch in able-bodied and SCI subjects
- Real-time implementation of double jaw clench mode switch in FES subject's computer-based EMG training program.

Rationale:

The four EMG electrodes do not provide enough independent command signals for simultaneous control of all degrees of freedom in the FES arm and hand system. However, all degrees of freedom of the upper limb neuroprosthesis can be controlled by sequentially controlling smaller subsets of dimensions. This requires a discrete switch that can be used to toggle between the different subsets of degrees of freedom as needed. For example, if one is only able to generate 2 simultaneous proportional command signals from the implanted EMGs, a discrete switch could be used to toggle control between 2D movements along a table top, and then switch into hand orientation, finger flexion extension mode, and then switch again to a command that brings the hand to the mouth. A rapid double jaw clench (DJC) can act as a robust discrete switch that is different than the EMG patterns generally found during eating or talking. It can also easily be detected in the first FES subject's auricularis EMGs.

Results:

One able-bodied subject generated DJCs on cue that were detected using EEG electrodes on the scalp. The SCI subject also generated DJCs on cue, but her signals were detected on the implanted EMG electrode over the auricularis muscle. Classifier functions were developed to identify DJCs from other types of EMG & EEG noise during offline analysis of the cued DJC signals. Linear descriminant analysis, neural networks, and support vector machines where all tested by building classifiers from the cued data, and evaluating the classifiers in an offline simulated 'real-time' analysis. All performed well in detecting true positives, but support vector machine performed best in eliminating false positives. The number of time points of data used by the classifiers to detect a double jaw clench were varied until an optimal value was found that minimized false positives and maximized true positives (optimal = 15 sequential time features input into the classifier). In data sets with only double jaw clenches, a true positive rate of 96% and false positive rate of 2% was achieved. On data with double jaw clenches while the subject was also chewing (used to evaluate the affect of eating) a true positive rate of 98% and false positive rate of 7% was achieved.

Show in Figure 4 below is an example of the algorithm classifying DJCs correctly while ignoring non-double jaw clench EMG noise from the implanted EMG electrodes in the subject with SCI.

Once a viable, DJC classifier was determined for the FES subject, a training program was developed to look for DJCs in real time and to 'select' targets based on the detection of DJCs during the 2D EMG-controlled cursor training program. This will allow the subject to practice integrating both 2D proportional control with the discrete mode switch while at home.

Discussion and interpretation:

The double jaw clenches can potentially provide a robust mode switch that is easy to do and cosmetically unobtrusive. The FES subject has been practicing this and seems to think this will work well for her. We should be able to reduce the false positive rates by increasing the threshold for detection. It is expected that, with more training, the subject will learn to produce even more robust double jaw clench signals. With current filter settings, the double jaw clench only makes minor deviations in the proportional 2D control, which also relies on the auricularis muscle.

Future plans:

The next step is to incorporate the DJC mode switch into the FES control system. Additionally, we will investigate other strategies for enabling the auricularis to be used for both proportional control and for the mode switch without one task interfering with another. This will most likely be accomplished by very briefly suppressing proportional control if a rapid rise in EMG value is detected. This also has the advantage of preventing unintended proportional commands during eating.

D. Concerns

There are no significant concerns at this time.

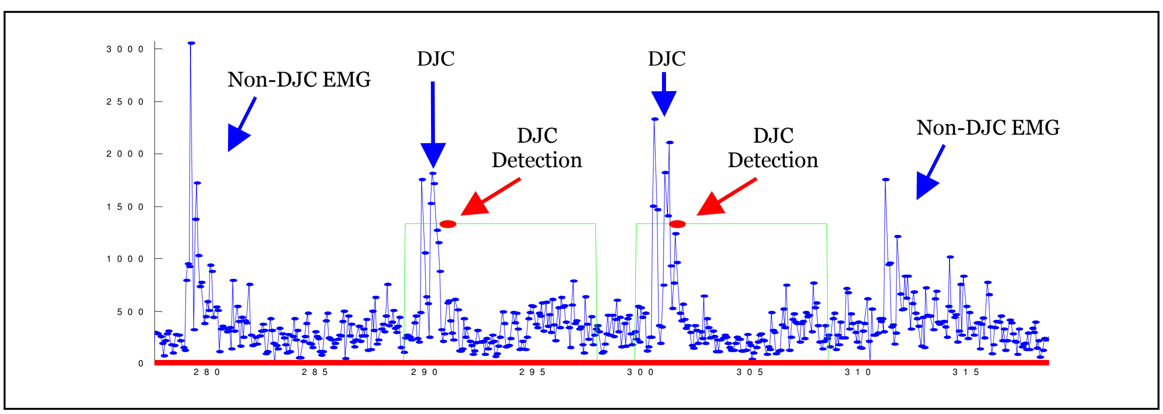

Figure 4. Blue line is auricularis EMG from FES subject. Green line indicates when a double jaw clench cue went on. Red dots indicate when the classifier detected the DJCs in real-time.